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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,749	05/31/2005	Jorge Setoain Quinquer	ABG 3002	1639

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EXAMINER	
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ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,749	QUINQUER ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/12/05; 8/17/05; & 5/15/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-4,6,7,9,10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,8 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/17/05 & 5/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

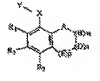
1. The Examiner acknowledges receipt of the amendment filed 5/15/09 wherein claims 1-3 were amended and claims 15-17 were added.

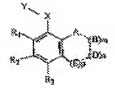
Note: Claims 1-17 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compounds, compositions, and uses thereof wherein the compounds have the formula as set forth in claims 5, 6, 7, 8, 9, and 10.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election with traverse of Group (7) filed 5/15/09 is acknowledged. The traversal is on the grounds that the special technical feature lies in that the compounds have the general formula  and metal complexes thereof. As a result, Applicant asserts that under 37 CFR 1.475, one is entitled to a product, process specifically adapted for the manufacture of the said product, and use of the said product. Hence, since Applicant has claims directed to such, it is Applicant's position that the claims in fact possess unity of invention and the rejection should be withdrawn. Applicant's arguments are non -persuasive for the following reasons. First, it should be a noted that a non-labeled species is distinct from a labeled species. The instant claims encompassed both labeled and non-labeled species. Secondly, it should be noted that



in the general formula the variable A is N or NR_4; B is CR_5, NR_5, or N; D is CR_6, NR_6, or N; and E is CR_7, NR_7, or N. The ring contains a maximum of two nitrogen atoms in the ring containing the A-substituent. The variables m, n, and p have a value of 0 or 1, wherein m + n + p = 2 or 3 (this means that if each variable has a value of 1, the ring containing the A-substituent has six-members and if the total of the three variable is 2, the ring containing the A-substituent has five-members). Thus, a ring containing five-members is different structurally from a ring containing six-members. Also, a ring containing one nitrogen atom is distinct from one having two nitrogen atoms. Thirdly, according to the unity of invention PCT Rule 13.2, where a group of invention is claimed in one and the same application, the requirement of unity of invention is fulfilled ***only*** when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' is interpreted to mean those technical features that define a contribution with each of the claimed invention, considered as a whole, made over the prior art. Thus, the cited prior art indicates that the instant invention lacks a special technical feature over the prior art. Hence, based on the explanations above, the claims do lack unity. As a result, it is proper to separate the claims into various groups as set forth in the office action mailed 4/1/09. The restriction requirement is still deemed proper and is therefore made FINAL.

Note: As set forth in the interview summary of record dated 4/15/09, Applicant is correct that the Examiner agreed that Groups (15) - (20), (23), and (24) should be deleted.

The Examiner also acknowledges receipt of the species 5-chloro-7-[123I]iodo-8-hydroxyquinoline.

The search was not expanded beyond Applicant's elected species because prior art was found which could be used to reject Applicant's claims.

WITHDRAWN CLAIMS

4. Claims 1-4, 6, 7, 9, 10, and 12-17 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 FIRST PARAGRAPH REJECTIONS

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 5, 8, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the

world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to all possible diagnoses of diseases associated with protein depositions that are compatible with the instant invention In addition, formula as set forth in claim 5 does not adequately describe the variable Y or Rph. Thus, what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above

are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 SECOND PARAGRAPH REJECTION

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 11: The claims as written are ambiguous because independent claim 5 is vague and indefinite. Specifically, (a) in line 6, the phrase 'Y represents H or, along with X where X = O, a carbohydrate' is confusing. Is Applicant saying that Y = H, O, S, or a carbohydrate radical? The phrase is confusing because Applicant is giving an additional definition of X (carbohydrate). Please clarify in order that one may ascertain what is being claimed. (b) In lines 22-25, the claim is confusing because of the phrase 'Rph...group;'. Specifically, the phrase is confusing because there is no Rph variable in the structure or variable definitions. (c) In lines 28-29, the claim is confusing because the variable X cannot be hydrogen. (d) In lines 30-31, the claim is confusing because the variables X and Y cannot be or contain a radioisotope. Furthermore, since claim 11 depends on claim 5, it is also vague and indefinite.

Claim 11: The claim as written is ambiguous because it is unclear for what diagnosis of diseases associated with protein deposition Applicant is claiming that are compatible with the instant invention.

102 REJECTION

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamberg et al (Nuklearmedizin, 1967, Vol. 6, No. 1, pp. 16-19).

Lamberg et al disclose 125I-labeled iodochloroxyquinoline which has the structure (the iodine is radioactive, 125-iodine) [see entire document, especially, page 16, first paragraph). The labeled iodochloroxyquinoline fulfills the requirement of the instant invention when Y = hydrogen; X = oxygen; A = nitrogen; m = 1; n = 1; p = 1; B =CR_5; D = CR_6; E = CR_7; R_5 = hydrogen; R_6 = hydrogen; R_7 = hydrogen; R_1 = 125-iodine; R_2 = hydrogen; and R_3 = chlorine. Thus, both applicant and Lamberg et al disclose overlapping subject matter.

103 REJECTION

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 5, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamberg et al (Nuklearmedizin, 1967, Vol. 6, No. 1, pp. 16-19) in view of Wilbur et al (US Patent No. 4,885,153) or in view of Baldwin et al (US Patent No. 4,279,887).

Lamberg et al disclose 125I-labeled iodochloroxyquinoline which has the structure (the iodine is radioactive, 125-iodine) [see entire document, especially, page 16, first paragraph). The labeled iodochloroxyquinoline fulfills the requirement of the instant invention when Y = hydrogen; X = oxygen; A = nitrogen; m = 1; n = 1; p = 1; B $=CR_5$; D = CR_6; E = CR_7; R_5 = hydrogen; R_6 = hydrogen; R_7 = hydrogen; R_1 = 125-iodine; R_2 = hydrogen; and R_3 = chlorine. However, while Lamberg et al disclose a

radioactive iodochloroxyquinoline compound, the reference fails to disclose other possible isotopes of iodine that may be used with the structure.

Wilbur et al disclose radiohalogenated proteins (see entire document, especially, abstract). In particular, the document is cited because it discloses that it is known in the art to replace any radioisotope of iodine (i.e., 123-iodine, 125-iodine, or 131-iodine) with another (column 3, lines 43-53).

Baldwin et al disclose agents useful for imaging (see entire document, especially, abstract). In particular, Baldwin et al is cited for its teaching that it is known in the art to replace any radioisotope of iodine (i.e., 123-iodine, 125-iodine, or 131-iodine) with another (column 2, lines 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lamberg et al using the teachings of Wilbur et al and Baldwin et al and replace the 125-iodine substituent with 123-iodine because the cited secondary references each disclose that 125-iodine and 123-iodine may be used interchangeably. Thus, replacing one iodine substituent with another is within the skill of a skilled artisan. Since each of the secondary documents discloses that 125-iodine and 123-iodine are interchangeable, a skilled artisan would be motivated to interchange one isotope for the other depending on the desired imaging being conducted.

COMMENTS/NOTES

15. Applicant's elected group, Group (7), is directed to compounds as set forth in independent claim 5 wherein one of A, B, D, or E is a nitrogen atom. Thus, since A is a

nitrogen atom, B, D, and E are carbon atoms. In addition, since Applicant's elected species is 5-chloro-7-[123I]iodo-8-hydroxyquinoline, the ring containing the A-substituent has six-members.

16. It is noted that the compound/composition of the prior art is the same as that being claimed by Applicant. Although the cited prior art does not disclose the particular use, the compound/composition would be capable of having the same use as Applicant's invention since a product and its properties are inseparable. Thus, Applicant's compound/composition, like the cited prior art, would be 'capable of' performing the same function (see claim 11, for example).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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/D L. Jones/
Primary Examiner
Art Unit 1618

June 3, 2009